

# **EXHIBIT F**



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Centers for Medicare &amp; Medicaid Services

*Administrator*

Washington, DC 20201

OCT 18 2006

John T. Montgomery  
 Ropes & Gray LLP  
 One International Place  
 Boston, MA 02110-2624

Re: Request for testimony of Nancy Ann Min De Parle, Thomas A. Scully and Stanley Weintraub in the matter of In re. Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456 (Civil Action: 01-CV-12257)

Dear Mr. Montgomery:

Thank you for your letter to Mark McClellan, M.D., Ph.D., Administrator of the Centers for Medicare & Medicaid Services ("CMS"), Department of Health and Human Services ("HHS"), in which you request that former Administrators Nancy Ann Min De Parle, and Thomas A. Scully, and former senior policy advisor, Stanley Weintraub provide testimony in the above-referenced litigation. Such requests are governed by HHS' rules regulating testimony of HHS employees and former employees in cases to which HHS is not a party.<sup>1</sup> 45 C.F.R. Part 2 (the "Touhy regulation"). The Touhy regulation requires that requests for testimony must be in writing and must state: 1) the nature of the requested testimony; 2) why the information sought is unavailable by any other means; 3) the reasons why the testimony would be in the interest of the Department. 45 C.F.R. § 2.4(a). The regulation also states that HHS will voluntarily comply with requests for testimony only if the Agency head, "after consultation with the Office of the General Counsel, [determines] that compliance with the request would promote the objectives of the Department." 45 C.F.R. § 2.3. As Acting Administrator, I am responsible for deciding whether to approve your request.

The usual concerns regarding testimony of former HHS employees is compounded by the nature of the former positions of these particular employees. Ms. Min De Parle and Mr. Scully are former Administrators of CMS and Mr. Weintraub was a policy advisor. You have asked that all three former employees be allowed to testify regarding the following: 1) knowledge or understanding of the use of average wholesale price ("AWP") for reimbursement; 2) the relationship between AWP and provider acquisition costs; 3) the extent to which reimbursement of drug ingredients operated as a cross-subsidy for the inadequate reimbursement of the costs of service and administration; 4) the reasons for maintaining AWP as part of Medicare reimbursement; and 5) the general operation of the Part B drug reimbursement system. Specifically, you seek the rationale behind Ms. Min De Parle's

<sup>1</sup> The United States intervened in the matter United States ex rel Ven-A-Care v. Abbott, which was transferred to MDL No. 1456. However, the United States is not a party to any other action in In re. Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456 (Civil Action: 01-CV-12257). Defendants' arguments to the contrary are baseless.

Page 2

statements to the Office of Inspector General ("OIG") and the House Ways and Means Committee. Similarly, Mr. Scully is being asked to testify regarding the policy and political reasons that Congress retained the AWP methodology for a period of time and then why such methodology was changed. Defendants also ask for Mr. Scully's testimony regarding general government knowledge and decision making regarding AWP. Finally, Mr. Weintraub's testimony is sought because, according to Defendants, he played a key role in drafting the 1991 proposed and final rules in the Federal Register setting drug reimbursement at the lower of estimated acquisition cost or AWP. After reviewing your request, I have determined that it does not satisfy the criteria set forth at 45 C.F.R. § 2.4 Accordingly, I have decided to deny your request that Ms. Min De Parle, Mr. Scully and Mr. Weintraub be allowed to testify at trial.

As a result of their positions with CMS, all three former employees were privy to information, including information covered by the attorney-client and deliberate process privilege, regarding CMS' use of the AWP benchmark as an element in Part B drug reimbursement. The government's position on the issue of AWP is contained in numerous agency and HHS documents, most, if not all of which were forwarded to Defendants, or are public documents accessible on the internet. For example, Mr. Scully's testimony is contained in the Reimbursement and Access to Prescription Drugs Under Medicare Part B:Hearing before the Subcommittee on Health Care of the Committee on Finance, 107<sup>th</sup> Cong. 6-9 (2002) (statement of Thomas A. Scully Administrator of CMS).<sup>2</sup> Ms. Min De Parle provided public comments to Office of Inspector General, OEI-03-97-00290, Report on Excessive Payments for Prescription Drugs (1997). The extent of Mr. Weintraub's knowledge and views, as a senior policy advisor at CMS, are also reflected in agency documents and the proposed and final rules relating to the issue of AWP published in the federal register. Therefore, Defendants' argument that the former employees' views on AWP cannot be obtained by other means is without merit.

To the extent you are asking the former Administrators to testify regarding the reasons for and development of their Congressional testimony and other public statements, such statements are the result of discussions between the former employees, senior advisors and counsel. Any testimony

---

<sup>2</sup> See also Reimbursement and Access to Prescription Drugs Under Medicare Part B:Hearing before the Subcommittee on Health Care of the Committee on Finance, 107<sup>th</sup> Cong. 30-32 (2002) (statement of Laura Dummit, Director, Health Care-Medicare Payment Issues, General Accounting Office) and issued a report entitled General Accounting Office, GAO-02-531T: Medicare Outpatient Drugs; Program Payments Should Better Reflect Market Prices (2002).

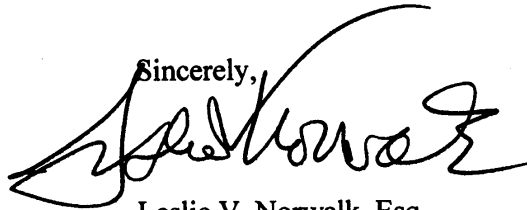
Page 3

regarding the development of such statements would compromise HHS' deliberative process and attorney client privileges.

The agency's use of AWP and its subsequent change to a different Part B drug reimbursement method resulted in numerous public hearings and reports on Medicare drug reimbursement, and are memorialized by statute and regulation. Statutory and regulatory intent is a matter of law to be decided on the basis of the language of the statute or regulation, and, if appropriate, on the public historical record of the legislation or regulation. The agency does not believe that the views of former employees regarding the meaning of statutory or regulatory terms are proper subjects for testimony. Thus, there is no furtherance of HHS goals in allowing such testimony.

If you have any questions about this decision, please contact Carol J. Bennett of the Office of General Counsel at (202) 205-9263.

Sincerely,

A handwritten signature in black ink, appearing to read "Leslie V. Norwalk", with a large, sweeping flourish extending from the end of the signature.

Leslie V. Norwalk, Esq.  
Acting Administrator

Page 4

**DRAFT**

Sent Via Telefax and U.S. Mail

Fax. (617) 951-7050